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(71) Applicant (for all designated States except US): MDC INVESTMENT HOLDINGS, INC. [US/US]; Suite 200, 900 Market Street, Wilmington, DE 19801 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): HALSETH, Thor, R. [US/US]; 367 Buckboard Circle, Simi Valley, CA 93065 (US). BOTICH, Michael, J. [US/US]; 2330 Eagle Creek Lane, Oxnard, CA 93030 (US). BARKER, John [US/US]; 2333 Aztec Avenue, Ventura, CA 93001 (US). HALL, Robert, L. [US/US]; 375 Larcom, Thousand Oaks, CA 91360 (US).

(74) Agent: ELAND, Stephen, H.; Dann, Dorfman, Herrell &amp; Skillman, Suite 720, 1601 Market Street, Philadelphia, PA 19103 (US).

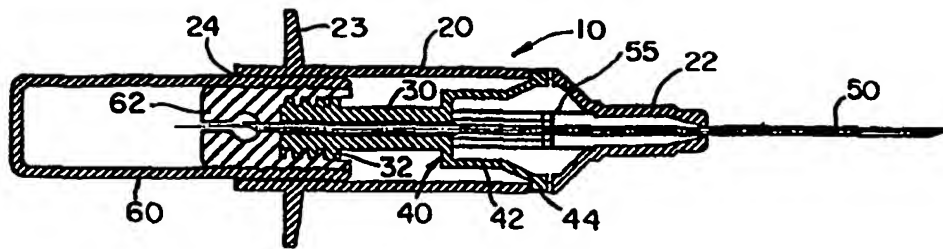
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(54) Title: PRE-FILLED RETRACTABLE NEEDLE INJECTION DEVICE



(57) Abstract

A needle-bearing device (10) for injecting medicinal fluid from a pre-filled vial is provided. After use, the needle (50) is retracted into the body of the device to prevent inadvertent contact with the sharpened end of the needle (50). In one embodiment, the invention provides a manually actuable button that effectuates retraction of the needle (50) after use. In another embodiment, retraction is effectuated automatically after the injection is complete.

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**PRE-FILLED RETRACTABLE NEEDLE INJECTION DEVICE**

Michael J. Botich  
Thor R. Halseth

**Field of the Invention**

The present invention relates to pre-filled vials, ampoules, carpules, or cartridges for administering injections of medicinal fluids to patients. More specifically, the invention relates to such devices having a retractable needle feature for rendering the device non-reusable and safely disposable.

**Background of the Invention**

Various types of medical devices employ a needle for piercing the skin of a patient for diagnostic or therapeutic purposes. One such device is a vial injector. Vial injectors utilize pre-filled vials that have a pre-measured dose of medication. The vial injector is used to inject the medication from the vial into a patient.

Handling of such needle-bearing medical devices after the needle is withdrawn from the patient can result in transmission of various pathogens, most notably human immune virus (HIV), to uninfected medical personnel, due to an inadvertent needle stick. Accordingly, it is desirable to provide a device for injecting medication from a pre-filled vial, wherein the injection needle is retracted into the housing of the device after use.

There are numerous retractable needle medical devices disclosed in the prior art. Typically, to effectuate retraction, the prior art devices require manual actuation by the operator. In many situations, such as an emergency situation, the operator is distracted or rushed so that the manual step necessary

to effectuate retraction is not performed, either intentionally or unintentionally. In such instances, the used needle remains exposed, creating a risk of an inadvertent needle stick. Therefore, it would be  
5 desirable to provide an automatic needle retraction mechanism in which needle retraction is effectuated by normal operation of the device without the need to perform a separate manual step. It is further desirable to provide a device with a limited number of  
10 components so that the device can be produced cost effectively.

#### Summary of the Invention

With the foregoing in mind, the present invention provides a medical device for injecting medicinal  
15 fluid from a fluid container, such as a vial, into a patient. The device includes a needle that is retracted automatically after use so that the contaminated sharpened tip of the needle is enclosed within the device to prevent inadvertent needle  
20 sticks.

The device includes a hollow housing having a generally open rearward end forming a socket. A vial containing a quantity of medicinal fluid is adapted to engage the socket. The needle for injecting the fluid  
25 is operable between a projecting position in which the sharpened tip of the needle projects forwardly from the housing and a retracted position wherein the sharpened tip is enclosed within the housing. A biasing element biases the needle toward the retracted  
30 position. A needle retainer releasably retains the needle in the projecting position. The needle retainer is operable between a locked position and an unlocked position. In the locked position, the needle retainer releasably retains the needle in the  
35 projecting position against the bias of the biasing

element. In the unlocked position, the needle is released allowing the biasing element to displace the needle rearwardly. The vial cooperates with the needle retainer so that upon forward displacement of the vial, the vial engages the needle retainer displacing the needle retainer from the locked position to the unlocked position.

### Description of the Drawings

All of the objects of the present invention are more fully set forth hereinafter with reference to the accompanying drawings, wherein:

Fig. 1 is a side sectional view of a vial injector having a retractable needle;

Fig. 2 is a top sectional view of the vial injector shown in Fig. 1;

Fig. 3 is a side sectional view of the vial injector shown in Fig. 1, illustrating the needle just prior to retraction;

Fig. 4 is a top sectional view of the vial injector shown in Fig. 1, illustrating the needle just prior to retraction;

Fig. 5 is a side sectional view of the vial injector shown in Fig. 1, illustrating the needle after retraction;

Fig. 6 is a top sectional view of the vial injector shown in Fig. 1, illustrating the needle after retraction;

Fig. 7 is an enlarged fragmentary view of an alternate embodiment of the device shown in Fig. 1, illustrating features for locking the needle in the retracted position;

Fig. 8 is a cross-sectional view of an alternate embodiment of a medical device for use in injecting medication from a vial;

Fig. 9 is a cross-sectional view of the device

shown in Fig. 8, illustrating the device in a position just prior to release of a safety latch;

Fig. 10 is a cross-sectional view of the device shown in Fig. 9, illustrating the device in a position just subsequent to release of the safety latch;

Fig. 11 is a cross-sectional view of the device shown in Fig. 8, illustrating the insertion needle in a retracted position;

Fig. 12 is an enlarged fragmentary cross-sectional view of the device shown in Fig. 9, illustrating details of the safety latch in a latched position; and

Fig. 13 is an enlarged fragmentary view of the device shown in Fig. 10, illustrating details of the safety latch in an unlatched position.

#### **Description of the Preferred Embodiment**

Referring now to the drawings in general and to Fig. 1 specifically, there is shown a vial injector 10 with an attached vial 60 that is pre-filled with medication. The vial injector 10 includes a needle 50 with a sharpened tip for inserting the needle into a patient. The needle 50 is in fluid communication with the medicine in the vial 60. By pressing the vial 60 into the vial injector 10, the medicine is expelled from the vial and into the patient through the needle 50. After the medicine is administered to the patient, the needle is retracted into body of the vial injector automatically.

Referring to Figs. 1-6, the device includes a generally cylindrical housing 20, a needle 50, a spring 55 biasing the needle rearwardly, and a needle retainer 40 releasably retaining the needle against the bias of the spring. The needle is operable between two positions, a projecting position and a retracted position. In the projecting position, the

needle 50 projects forwardly from the forward end of the housing 20. In the retracted position, the needle is retracted into the housing 20 so that the sharpened tip of the needle is enclosed within the housing to prevent inadvertent contact with the sharpened tip. When the needle is in the projecting position, as shown in Fig. 1, the spring biases the needle rearwardly toward the retracted position. The needle retainer 40 releasably retains the needle in the projecting position, against the bias of the spring. The needle retainer cooperates with the vial 60, so that when the vial is displaced forwardly during injection of the medicine, the needle retainer automatically releases the needle and the needle retracts into the housing, as shown in Figs. 5 and 6.

As shown in Fig. 1, the spring 55 circumscribes the needle 50. A forward end of the spring bears against the interior of the forward portion of the nose 22. The rearward end of the spring bears against the forward end of the plunger 30.

Referring now to Figs. 1-4, the elements of the device 10 will be described in greater detail. The housing is generally cylindrical and the forward end of the housing has a reduced diameter tapered nose 22. The nose 22 has an opening through which the needle 50 projects outwardly from the housing 20 so that the sharpened tip of the needle can be inserted into a patient for administering medication to the patient. Prior to use, a needle cap encloses the portion of the needle 50 projecting from the housing. The rearward end of the housing 20 is open, forming a cylindrical socket 24 for receiving the vial 60. Two laterally extended flanges 23 project outwardly from the housing 20, transverse the longitudinal axis of the housing, forming two finger grips for operating the device. The housing further includes a pair of locking apertures 26 that cooperate with the needle retainer

as described further below.

A plunger 30 is disposed within the housing 20. The needle 50 is fixedly attached to the plunger 30. Specifically, the plunger 30 is a generally  
5 cylindrical element having a central bore. The needle is a double ended needle, so that both ends of the needle are sharpened. The needle 50 is disposed within the central bore of the plunger so that the forward portion of the needle projects forwardly from  
10 the plunger and the rearward portion of the needle projects rearwardly from the plunger. The needle can be attached to the plunger in one of several ways. For instance, the needle 50 may be attached to the plunger 30 by an adhesive such as a UV curable epoxy.  
15 Alternatively, the needle can be molded into the plunger, which is formed of plastic. The rearward end of the plunger 30 forms a stem 32 configured to cooperate with the vial 60, as discussed further below.

20 The plunger 30 is axially displaceable within the housing 20. Prior to retraction, the plunger is retained in a fixed axial position. The plunger is retained in this fixed position while the medication is being expelled from the vial 60. After use, the  
25 plunger and the attached needle are displaced rearwardly.

The needle retainer 40 is operable between a locked position and an unlocked position. In the locked position, the needle retainer 40 releasably  
30 retains the plunger 30 and the attached needle 50 in a fixed axial position so that the needle projects forwardly from the housing 20. More specifically, in the locked position the needle retainer engages the housing 20, to retain the plunger 30 and the attached  
35 needle against the rearward bias of the spring 55. In the unlocked position, the needle retainer allows the plunger 30 and the needle 50 to be retracted

rearwardly. More specifically, in the unlocked position, the needle retainer disengages the housing, so that the spring 55 can propel the needle and the attached plunger rearwardly.

5       The needle retainer 40 comprises a pair of the elongated resilient arms 42. The arms project forwardly and radially outwardly into engagement with the locking apertures 26 formed in the side of the housing 20. The terminal end of each arm forms a  
10       locking tab or detent 44. The locking tabs project into the apertures 26 of the housing 20. Each aperture forms a lip or rim. The locking tabs 44 engage the lip formed by each aperture. In this way, the locking tabs 44 operate as a pair of latches to  
15       retain the plunger 30 and the attached needle 50 against the bias of the spring 55.

Referring again to Figs.1 and 3, the rearward end of the housing 20 is generally opened, forming a socket for receiving the vial 60. The vial 60 is a  
20       generally cylindrical vessel containing an amount of medicinal fluid. In the present instance the vial is formed of a rigid material such as glass. The rearward end of the vial 60 is closed, and the forward end of the vial is sealed by a rubber piston or plug  
25       62. The plug 62 is generally cylindrical having a plurality of axially-spaced circumferential ribs that form a fluid-tight seal between the plug 62 and the internal surface of the vial 60.

The plug 62 is configured to cooperate with the  
30       mounting stem 32 of the device 10. In the present instance, the mounting stem 32 is externally threaded and the plug 60 has corresponding internal threads. The interior end of the plug 62 adjacent the medication includes a recess. In this way, a  
35       pierceable wall is formed in the plug 62 between the recess and the base of the internal threads. When the vial 60 is mounted on the mounting stem 32, the

rearward sharpened end of the needle 50 pierces the wall of the plug and extends into the recess formed in the interior of the plug. The recess opens to the interior of the vial 60 so that when the needle 50 projects into the recess, the needle is in fluid communication with the interior of the vial 60, allowing medication to flow from the vial into the needle. After the needle pierces the wall of the plug, the wall forms a fluid-tight seal between the plug 62 and the side of the needle to prevent medication from leaking into the housing 20.

The medication is expelled from the vial 60 by moving the vial axially forwardly to advance the vial. The plug 62 is mounted on the mounting stem 32 so that the plug remains stationary while the vial 60 is advanced. The plug 62 is configured to form a sliding fit with the interior of the vial so that the vial can slide over the plug to expel the medication from the vial. Additionally, the circumferential ribs maintain a fluid tight seal between the plug and the vial while the vial slides over the plug.

As the vial 60 is advanced, the medication in the vial flows out of the vial and into the needle. The medication is expelled from the needle into the patient. As described further below, after the medication is injected into the patient, the needle 50 is retracted into the housing 20 so that the forward sharpened tip of the needle is enclosed within the housing 20.

Referring now to Figs. 3-6, the actuation of the needle retainer 40 arm is most clearly shown. The forward end of the vial 60 forms a rim. As the vial 60 is axially advanced, the rim of the vial is displaced into engagement with the arms 42 of the needle retainer 40. The vial is configured so that the distance between the rearward end of the seal and the rearward end of the vial corresponds to the

distance between the rim of the vial and the needle  
retainer arms 42 when the vial is mounted on the  
mounting stem 32. In this way, the rim of the vial 60  
engages the needle retainer arms 42 when substantially  
5 all of the medication is expelled from the vial 60.  
After the rim of the vial 60 engages the needle  
retainer arms 42, continued axial advancement of the  
vial displaces the arms 42 radially inwardly so that  
the locking tabs 44 are displaced inwardly,  
10 disengaging the locking tabs 44 from the locking  
apertures 26 of the housing 20. In this way, the vial  
operates as an actuator such that axial advancement of  
the vial displaces the needle retainer into the  
unlocked position. The spring is of sufficient force  
15 to overcome the friction between the locking tabs 44  
and the interior of the housing 20. After the needle  
retainer is in the unlocked position and the user  
releases the vial, the spring 55 propels the needle 50  
rearwardly until the forward sharpened tip of the  
20 needle is enclosed within the housing 20.

As shown in Figs. 5 and 6, when the needle is  
retracted, the needle, the plunger, and the vial are  
displaced rearwardly together. Accordingly,  
preferably the device includes a mechanism for  
25 limiting the rearward travel of the retracted  
elements. In addition, preferably the device includes  
an element for limiting the forward displacement of  
the needle after retraction to prevent the  
contaminated needle from being re-extended from the  
30 housing.

Referring now to Figs. 2, 4 and 6, the device 10  
includes a guide arm 38 that cooperates with an  
alignment slot 28 formed in the bottom of the housing.  
The guide arm 38 is integrally formed with the plunger  
35 30, and projects radially outwardly into engagement  
with the alignment slot 28 formed in the housing 20.  
The guide arm 38 cooperates with the alignment slot 28

to constrain the plunger against circumferential displacement relative to the housing. In this way, the plunger is limited to axial displacement. As shown in Fig. 6, the rearward end of the guide slot 28  
5 operate as rearward stops limiting the rearward displacement of the plunger and the attached needle. In addition, the rearward portion of the alignment slot forms a lockout window that the guide arm 38 engages at the rearward-most point of retraction. The  
10 lockout window retain the guide arm 38 against forward displacement, so that the plunger and the attached needle cannot be displaced forwardly.

Configured as described above, the device 10 operates as follows. Prior to use, the needle 50 is  
15 disposed in the projecting position so that the sharpened forward tip of the needle is exposed. The needle is inserted into the patient. The vial 60 is then depressed to axially advance the vial, thereby injecting the medicinal fluid from the vial into the  
20 patient. At the end of the injection stroke, the vial displaces the needle retainer arms 42 radially inwardly thereby actuating the needle retainer to the unlocked position. However, the needle does not retract until the medical professional releases the  
25 vial. Once the vial is released, the spring 55 then propels the needle 50 rearwardly so that the contaminated forward sharpened tip of the needle is enclosed within the housing. Accordingly, the medical professional can retain pressure on the vial until  
30 after the needle is withdrawn from the patient. The medical professional can then release his or her finger pressure on the vial so that the spring automatically retracts the needle. Alternatively, the medical professional can release his or her finger  
35 pressure on the vial after the needle retainer is unlocked and while the needle is still inserted into the patient. The spring 55 then retracts the needle

50, thereby withdrawing the needle from the patient and into the housing.

Referring, to Fig. 7, the device can be modified by utilizing a guide recess formed in the inner wall of the housing instead of a guide slot. In such an arrangement the guide arm 38 projects into and cooperates with the recess. In addition, a rearward stop 29 is formed at the rearward end of the recess. The forward face of the stop is tapered so that the guide arm 38 can deflect inwardly and ride over the stop. However, the rearward face of the stop is generally normal to the recess, so that the guide arm cannot readily be displaced forwardly. Alternatively, a rearward locking aperture can be located at the rearward end of the recess. When the guide arm is displaced rearwardly the guide arm engages the locking apertures to retain the plunger and the attached needle against forward or rearward displacement. In addition, the foregoing embodiment has been described as having a single guide arm 38. However, one or more additional guide arms can be utilized.

Referring now to Figs. 8-14 in general, and to Fig. 8 specifically, an alternate embodiment of a Vial injector 110 is shown. The vial injector 110 includes two needles, an insertion needle 114 and a rearward needle 116 that pierces a plug 190 that seals the vial 170. The insertion needle 114 is operable to inject medication into a patient, and is releasably retained by a needle retainer 150. An actuator 130 cooperates with the needle retainer 150 such that forward axial displacement of the actuator 130 causes the needle retainer 150 to release the insertion needle 114. A spring 160 then propels the insertion needle 114 rearwardly so that the sharpened tip of the needle is located within the vial injector.

The vial injector 110 includes a generally cylindrical hollow barrel 120 having a forward reduced

diameter tip 122. The tip 122 is generally closed having a orifice through which the insertion needle 114 projects. The rearward end 124 of the barrel 120 is generally open and is sized to receive the vial  
5 170.

The needle retainer 150 is positioned within the forward end of the barrel 120, adjacent the tip 122. The needle retainer 150 releasably retains the insertion needle 114 so that the insertion needle  
10 projects forwardly from the barrel 120 as illustrated in Fig. 8. The needle retainer 150 can be attached to the barrel 120 in a variety of ways, including ultrasonic welding, epoxy, or a snap fit. In the present instance, the needle retainer 150 is attached  
15 to the barrel 120 by way of a snap fit.

The insertion needle 114 projects through an axial bore in the needle retainer 150. The needle retainer includes a generally cylindrical body portion 152 at the forward end of the needle retainer and a  
20 plurality of axially elongated fingers 154 that releasably retain the insertion needle 114. The fingers 154 have radially inwardly directed protrusions forming a constricted portion in the bore of the needle retainer. Preferably, the surface of  
25 each protrusion is configured to conform to the outer surface of insertion needle 114 to maintain the needle in axial alignment with the needle retainer 150. The surfaces of the protrusions preferably form a continuous surface within the interior of the needle  
30 retainer to improve engagement with the insertion needle.

The fingers 154 are secured or bonded to the outer surface of the insertion needle 114 using an adhesive such as an epoxy. The needle retainer 150  
35 preferably includes four fingers 154, but one or more fingers 154 may be employed depending on such factors as the size of the device and the nature of the

biasing member. The exterior of the needle retainer 150 is provided with longitudinal grooves or score lines between the fingers 154 to facilitate separation of the fingers when retraction of the needle is actuated.

Alternatively, the needle retainer 150 can utilize a latching arrangement rather than being releasably bonded to the needle. In the latching arrangement, a block is affixed to the insertion needle 114. The ends of the needle retainer fingers 154 form inwardly directed latches that engage the block to releasably retain the insertion needle.

The needle retainer 150 retains the insertion needle 114 against the rearward bias of a spring 160. In the present instance, the spring 160 is a coil spring that circumscribes the insertion needle 114. As shown in Fig. 8, the forward end of the spring 160 bears against the interior of the barrel tip 122. The rearward end of the spring 160 is attached to the insertion needle 114, preferably by a UV curable adhesive. Alternatively, if the latching arrangement is utilized for the needle retainer 150, then the spring can bear against the block fixed to the needle, if desired.

The vial injector 110 includes an actuator 130 that is operable to engage the needle retainer 150 to cause the needle retainer to release the insertion needle 114 so that the spring 160 propels the insertion needle rearwardly. The actuator 130 is an elongated generally cylindrical member having a hollow axial bore 132. The axial bore 132 has two diameters. The forward portion of the axial bore has a major diameter that is larger than the diameter of the rearward portion of the axial bore. The forward end of the actuator 130 is generally open for receiving the rearward end of the insertion needle 114 that extends into the axial bore 132 of the actuator.

A mounting stem 138 is connected to the rearward end of the actuator 130. Preferably, the mounting stem 138 is integrally formed with the actuator 130. In the present instance, the mounting stem 138  
5 includes an externally threaded portion for threadedly engaging a plug 190 in the vial 190. A rearward needle 160 for piercing the plug 190 of the vial 170 projects rearwardly from the mounting stem 138. The rear needle 116 is fixedly connected to the actuator  
10 130, preferably by a UV curable adhesive. The forward portion of the rear needle 114 projects into the axial bore 132 of the actuator 130. Preferably, the rear needle 114 has an internal bore that is larger than the external diameter of the insertion needle 114. In  
15 this way, the insertion needle 114 is slidably displaceable within the rear needle 116.

As shown most clearly in Fig. 12, a seal 146 provides a fluid tight seal between the insertion needle 114 and the rear needle 116. The rear portion  
20 of the seal 146 includes a bore sized to receive the forward end of the rear needle 116. The forward portion of the seal 146 includes a constricted portion sized to receive the smaller diameter insertion needle 114, providing a fluid tight seal around the external  
25 surface of the insertion needle.

The forward end 136 of the actuator 130 is configured to cooperate the rearward end of the fingers 154 of the needle retainer 150. In the present instance, the forward end 136 of the actuator  
30 forms a tapered or frustoconical surface. The rearward end of each needle retainer finger 154 tapers radially inwardly so that the rearward end of the needle retainer 150 forms a convergingly tapered annular surface 156. Configured in this way, as shown  
35 in Figs. 9 and 10, when the actuator 130 is axially displaced forwardly to engage the needle retainer 150, the cooperating tapered surfaces of the actuator and

the needle retainer operate as a wedge to displace the needle retainer fingers 154 radially outwardly so that the needle retainer releases the insertion needle 114. The spring 160 then propels the insertion needle 114 rearwardly so that the sharpened point of the insertion needle is located within the housing beyond the reach of the operator.

The vial injector 110 preferably includes at least one, and preferably two, safety latches 140 that prevent the actuator 130 from being displaced forwardly until some, and preferably substantially all, of the medication is expelled from the vial 170. Each safety latch 140 is attached to the actuator 130, and in the present instance, the safety latches are integrally formed with the actuator. Each safety latch 140 is a flexible generally L-shaped arm. The forward end of the safety latch 140 is attached to the actuator 130 and the safety latch extends rearwardly. Each safety latch includes a detent 142 that cooperates with an aperture 126 formed in the wall of the barrel 120. In this way, as shown in Fig. 9, when the detent 142 of the safety latch 140 projects into the aperture 126, the safety latch 140 prevents the actuator 130 from being displaced axially forwardly.

Referring now to Fig. 12, preferably, the forward end of the detent 142 and the forward end of the aperture 126 are matingly tapered to improve the locking engagement of the detent with the aperture. The portion of the safety latch rearward of the detent 142 projects radially inwardly toward the actuator 130, forming a release tab 144. The forward end or rim 172 of the vial 170 cooperates with the release tab 144 to release the safety latch 140 as will be discussed further below.

Referring again to Fig. 8, the rearward end of the barrel 120 is generally opened, forming a socket 124 for receiving the vial 170. The vial 170 is a

generally cylindrical vessel containing an amount of medicinal fluid. The rearward end of the vial 170 is closed, and the forward end of the vial is open forming a rim 172. The open end of the vial 170 is sealed by a rubber piston or plug 190. The plug 190 is generally cylindrical having a plurality of axially-spaced circumferential ribs 192 that form a fluid-tight seal between the plug 190 and the internal surface of the vial 170.

10       The forward or external end of the plug is configured to cooperate with the mounting stem 138 of the vial injector. In the present instance, the mounting stem 138 is externally threaded and the plug 190 has corresponding internal threads. The interior  
15       end of the plug 190 adjacent the medication includes a recess 196. In this way, a piercable wall is formed in the plug 190 between the recess 196 and the base of the internal threads. When the vial 170 is mounted on the mounting stem 138, the rear needle 116 pierces the  
20       wall of the plug and extends into the recess 196 formed in the interior of the plug. The recess opens to the interior of the vial 170 so that when the rear needle 116 projects into the recess 196, the rear needle is in fluid communication with the interior of  
25       the vial 170, allowing medication to flow from the vial into the rear needle. After the rear needle 116 pierces the wall of the plug, the wall forms a fluid-tight seal between the plug 190 and the side of the rear needle to prevent medication from leaking into  
30       the barrel 120.

      The medication is expelled from the vial 170 by moving the vial axially forwardly to advance the vial. The plug 190 is mounted on the mounting stem 138 so that the plug remains stationary while the vial 170 is  
35       advanced. The plug 190 is configured to form a sliding fit with the interior of the vial so that the vial 170 can slide over the plug to expel the

medication from the vial. Additionally, the circumferential ribs 192 maintain a fluid-tight seal between the plug and the vial while the vial slides over the plug.

5       As the vial 170 is advanced, the medication in the vial flows out of the vial and into the rear needle 116. From the rear needle 116, the medication flows into the insertion needle 114 and then into the patient. After the medication is injected into the  
10       patient, the insertion needle 114 can be retracted into the housing 120 as follows.

Referring now to Figs. 9-11, when at least substantially all of the medication is expelled from the vial 170, the forward rim 172 of the vial engages  
15       the release tab 144 of each safety latch 140. Continued forward displacement of the vial 170 flexes each safety latch 140, displacing the safety latches radially inwardly thereby withdrawing the detents 142 from the apertures 126 in the barrel 120. After the  
20       detents 142 are withdrawn from the apertures 126, continued forward displacement of the vial 170 displaces the actuator 130 axially forwardly. The actuator 130 then engages the needle retainer 150 to release the insertion needle 114 as shown in Fig. 12  
25       and described previously. In this way, the safety latches 140 prevent the forward axial displacement of the actuator 130 preferably until at least substantially all of the medication is expelled from the vial 170. After at least substantially all of the  
30       medication has been expelled from the vial 170, the safety latch 140 releases the actuator allowing the actuator 130 to engage the needle retainer 150 to release the insertion needle 114.

As shown in Fig. 11, the spring 160 propels the  
35       insertion needle 114 rearwardly so that the insertion needle telescopes within the rear needle 116. In addition, as shown in Fig. 11, preferably the barrel

120 includes a reduced diameter forward portion forming an internal annular shoulder 125 that engages the forward portion of the safety latches 140. In this way, the internal shoulder 125 acts as a stop to prevent further forward axial displacement of the actuator.

The terms and expressions which have been employed are used as terms of description and not of limitation. There is no intention in the use of such terms and expressions of excluding any equivalents of the features shown and described or portions thereof. It is recognized, however, that various modifications are possible within the scope and spirit of the invention. For instance, the second embodiment described above can include a manually actuatable release for releasing the safety latches 140 so that the actuator can be actuated to effectuate retraction before substantially all of the medication is expelled from the vial. Accordingly, the invention incorporates variations that fall within the scope of the following claims.

**That Which Is Claim Is:**

1. A medical device, comprising:
  - a hollow housing having a generally open rearward end forming a socket;
  - a fluid container containing a quantity of medicinal fluid, the fluid container being adapted to engage the socket;
  - a needle having a sharpened tip, wherein the needle is operable between a projecting position in which the sharpened tip projects forwardly from the housing and a retracted position wherein the sharpened tip is enclosed within the housing;
  - a biasing element biasing the needle toward the retracted position;
  - a needle retainer operable between a locked position in which the needle retainer releasably retains the needle in the projecting position against the bias of the biasing element and an unlocked position in which the needle is released allowing the biasing element to displace the needle rearwardly;wherein upon forward displacement of the fluid container, the fluid container engages the needle retainer displacing the needle retainer from the locked position to the unlocked position.
2. The device of claim 1, wherein the needle retainer comprises a latch biased radially outwardly, releasably engaging the housing.
3. The device of claim 1 comprising a seal sealing the fluid container and a mounting stem adapted to engage the seal, wherein the seal and mounting

stem are retained against axial displacement while fluid is expelled from the fluid container.

4. The device of claim 3 wherein rearward displacement of the needle displaces the seal and mounting stem.

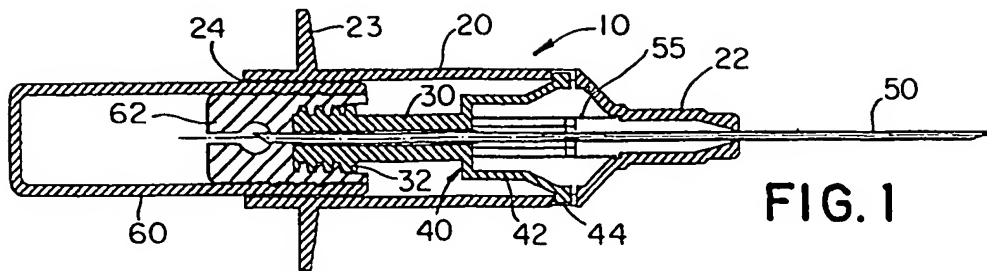


FIG. 1

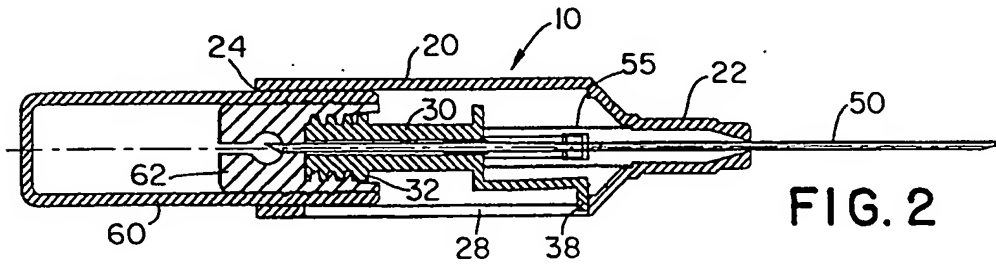


FIG. 2

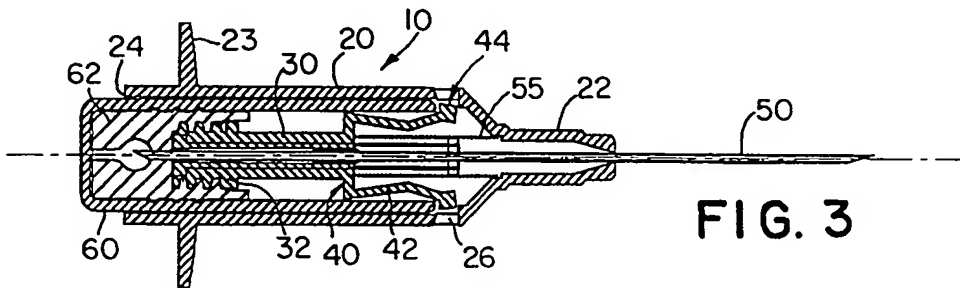


FIG. 3

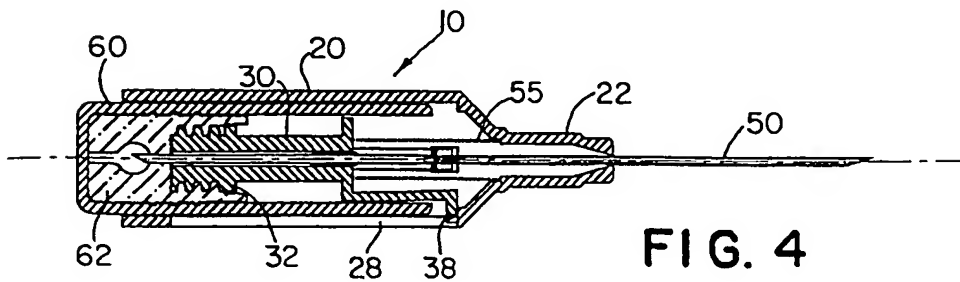
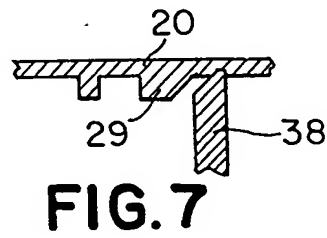
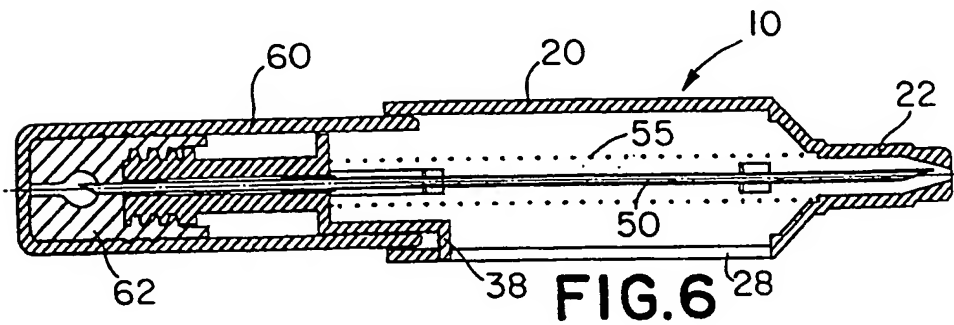
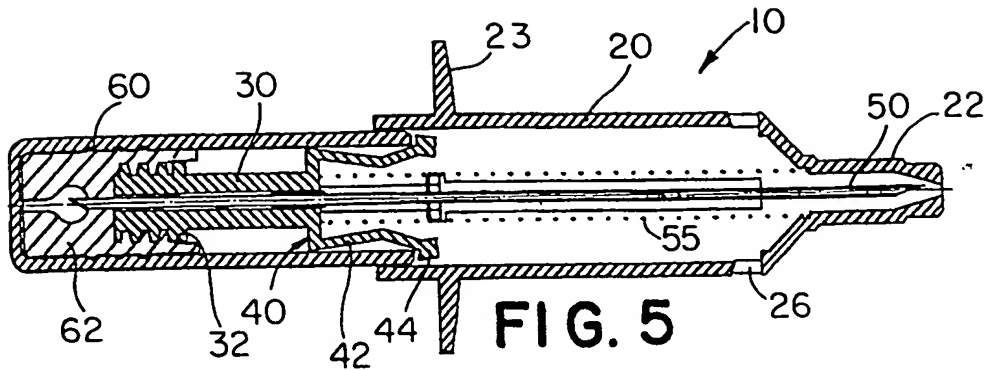
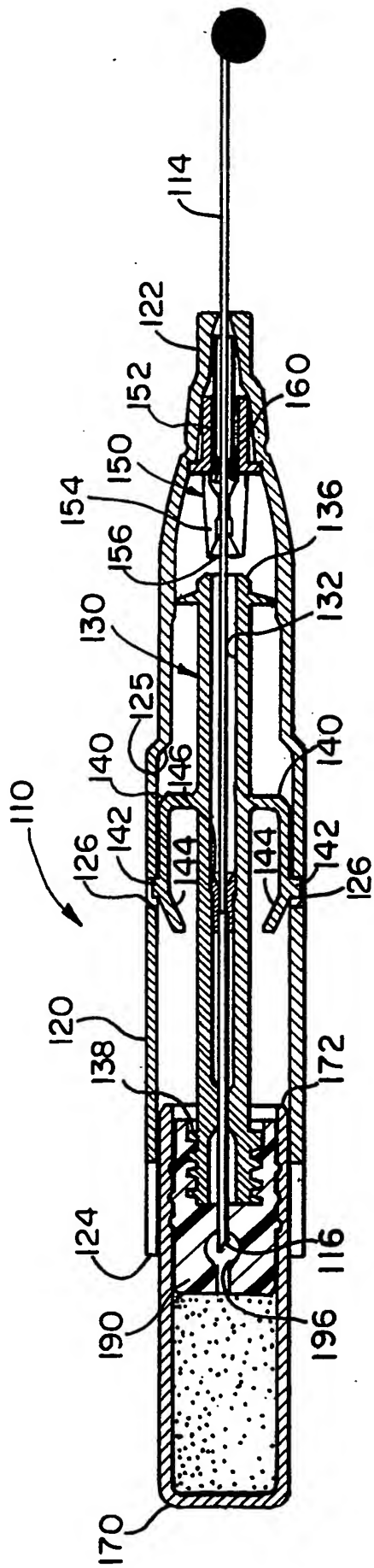
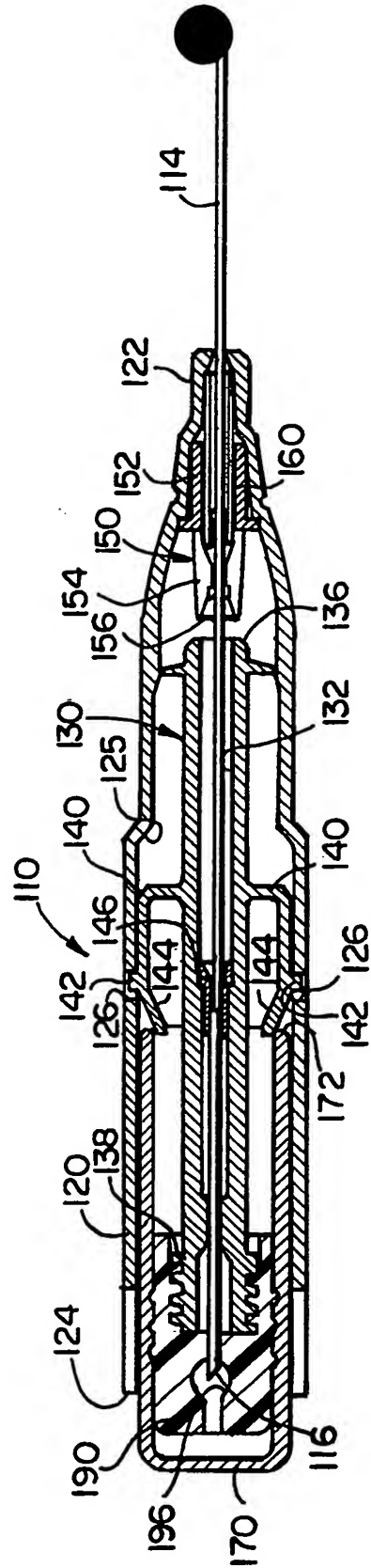


FIG. 4





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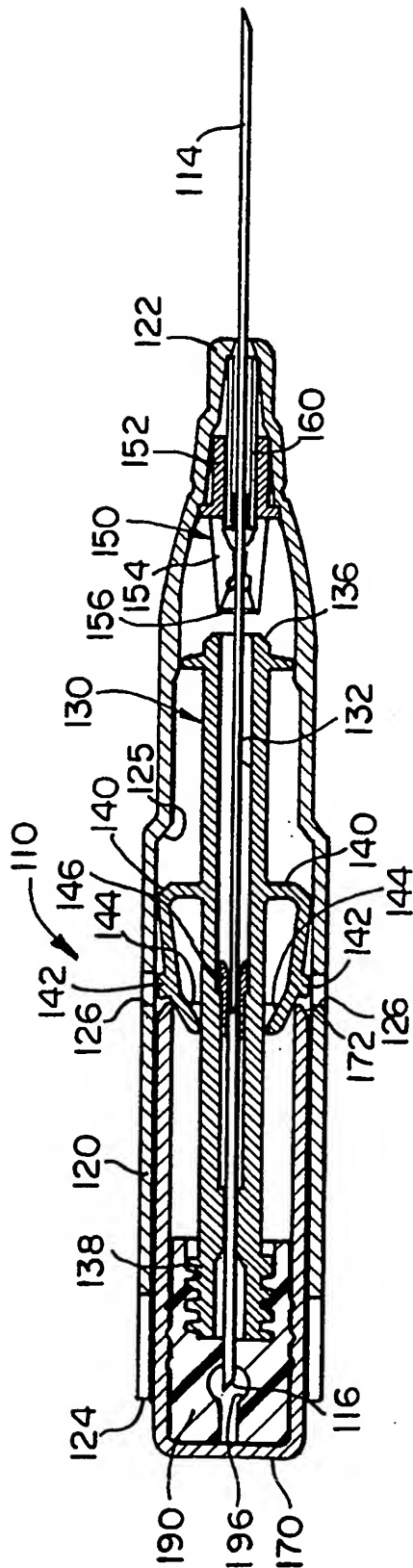


Fig. 10

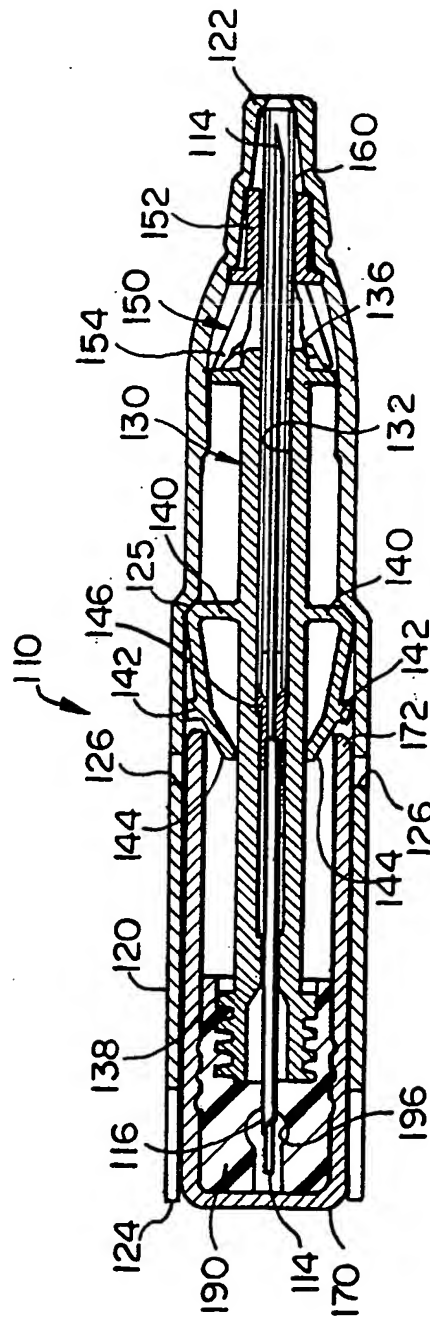
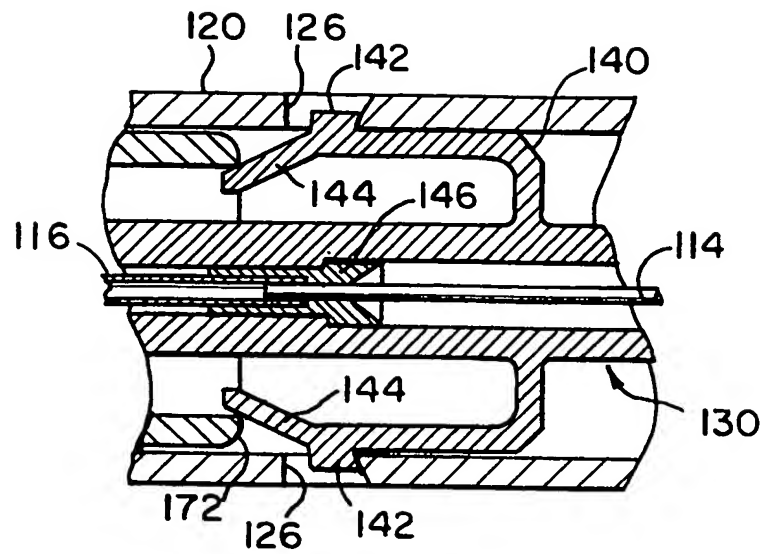
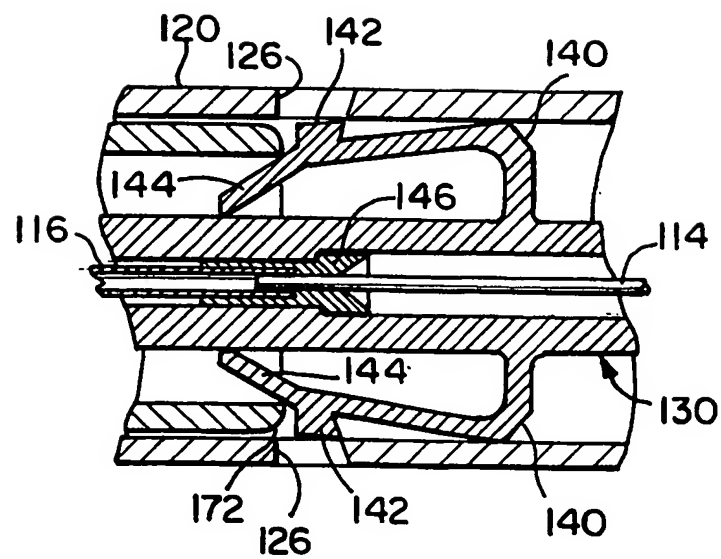


Fig. 11

**FIG. 12****FIG. 13**

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US99/04456

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :A61M 5/32

US CL :604/195

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/110, 181, 187, 195, 200, 201, 203, 205, 218, 220, 221, 231-234, 244

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,407,431 A (BOTICH et al) 18 April 1995, Figs. 10-12, specification.	1, 3, 4
Y	US 5,478,324 A (MEYER) 26 December 1995, Fig. 1, and specification.	1

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Further documents are listed in the continuation of Box C.

☐

See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

03 JUNE 1999

Date of mailing of the international search report

18 JUN 1999

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

CRIS L. RODRIGUEZ

Telephone No. (703) 308-2194

Findings of SO Follow-Up Audit - Aul de Fort

Client: Borealis Inc.  
 Audit: Borealis Inc.  
 Date of report: 12/12/2023  
 Date of report: 12/12/2023  
 Auditors: Borealis Inc.  
 Auditors: Borealis Inc.

Number	Findings	Type (NCR, NCR, COCOPOLITE)	Actions	Responsibility
AV-01-01	Findings in an emergency inventory that specifies the number, type and location of inventory.	COCOPOLITE	None Reported	
AV-01-02	Open burning	OS	The site should develop a plan for open burning of waste materials and ensure that the plan is implemented. The plan should include the following: 1. Identification of waste materials to be burned. 2. Identification of the location where the waste materials will be burned. 3. Identification of the personnel responsible for the burning. 4. Identification of the equipment to be used. 5. Identification of the safety measures to be taken. 6. Identification of the environmental impact assessment to be conducted. 7. Identification of the monitoring and reporting requirements. 8. Identification of the record keeping requirements. 9. Identification of the training requirements. 10. Identification of the emergency response plan. The plan should be reviewed and updated annually.	
AV-01-03	None	OS	None Reported	
AV-01-04	OS Substances register	OS	The facility should maintain a register of all substances used in the facility. The register should include the following information: 1. Name of the substance. 2. Quantity of the substance. 3. Location of the substance. 4. Date of receipt. 5. Date of expiry. 6. Name of the supplier. 7. Name of the recipient. 8. Name of the person responsible for the register. The register should be reviewed and updated annually.	
AV-01-05	OS	OS	None Reported	
AV-01-06	OS	OS	None Reported	
AV-01-07	OS	OS	None Reported	
AV-01-08	OS	OS	None Reported	
AV-01-09	OS	OS	None Reported	
AV-01-10	OS	OS	None Reported	
AV-01-11	OS	OS	None Reported	
AV-01-12	OS	OS	None Reported	
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AV-01-94	OS	OS	None Reported	
AV-01-95	OS	OS	None Reported	
AV-01-96	OS	OS	None Reported	
AV-01-97	OS	OS	None Reported	
AV-01-98	OS	OS	None Reported	
AV-01-99	OS	OS	None Reported	
AV-01-100	OS	OS	None Reported	

Number	Agency	Description	Finding	Type (105, 106, 107, 108)	Expiry Date (11, 12, 13, 14, 15)	Actions	Responsibility
WW-03-D1	Waterworks Water Management	Water management permit	Chlorine water management permit from ERM for water and wastewater water management permit was not renewed. The permit was renewed during the audit.	Water Law 13 790	The facility requested the renewal of the permit. The permit was renewed during the audit.	Not required	
WW-03-D1	Waterworks Water Management	Operating Permit	Operating Permit (Renewed in ERM)	Water Law 7772, State Decree 384/21	The facility requested the renewal of the permit. The permit was renewed during the audit.	Not required	
WW-03-D2	Waterworks Water Management	Permit for drinking water management	Permit for drinking water management (Renewed in ERM)	Water Law 7772, State Decree 384/21	The facility requested the renewal of the permit. The permit was renewed during the audit.	Not required	
WW-03-D3	Waterworks Water Management	Permit for drinking water management	Permit for drinking water management (Renewed in ERM)	Water Law 7772, State Decree 384/21	The facility requested the renewal of the permit. The permit was renewed during the audit.	Not required	
WW-03-D4	Waterworks Water Management	Water management permit	Water management permit (Renewed in ERM)	Water Law 13 790	The facility requested the renewal of the permit. The permit was renewed during the audit.	Not required	
WW-03-D5	Waterworks Water Management	Water management permit	Water management permit (Renewed in ERM)	Water Law 13 790	The facility requested the renewal of the permit. The permit was renewed during the audit.	Not required	
WW-03-D6	Waterworks Water Management	Water management permit	Water management permit (Renewed in ERM)	Water Law 13 790	The facility requested the renewal of the permit. The permit was renewed during the audit.	Not required	
WW-03-D7	Waterworks Water Management	Water management permit	Water management permit (Renewed in ERM)	Water Law 13 790	The facility requested the renewal of the permit. The permit was renewed during the audit.	Not required	



Number	Aspect	Description	Finding	Type (SE, PE, CE, NE)	Status (Per 14.03)	Actions	Responsibility
14.02.03.02	Urgency	Notification / Evaluation	Program and related a written Emergency Program that includes all activities	ME.17	Notification activities were performed by CHDO Company in April 2020. The program was updated in 2021 (2021) and includes all activities. The program was updated in 2021 (2021) and includes all activities. The program was updated in 2021 (2021) and includes all activities.	Program and related a written Emergency Program that includes all activities	
14.02.03.01	Warning / Warning	False prevention	Program floor cleaning in the Recreational and Living, Canada Area to prevent fire in the area	ME.18	GO implemented the program in January 2020. During the COVID-19 pandemic, the program was updated in 2021 (2021) and includes all activities.	Program floor cleaning in the Recreational and Living, Canada Area to prevent fire in the area	
14.02.03.02	Warning / Warning	False prevention	Recreational and Living / Living in the facility. The distance between radiators was not maintained. No safety was maintained in the area of the Canada Area. The distance between radiators was not maintained. No safety was maintained in the area of the Canada Area.	ME.19	The safety was not maintained. The distance between radiators was not maintained. No safety was maintained in the area of the Canada Area. The distance between radiators was not maintained. No safety was maintained in the area of the Canada Area.	Recreational and Living / Living in the facility. The distance between radiators was not maintained. No safety was maintained in the area of the Canada Area. The distance between radiators was not maintained. No safety was maintained in the area of the Canada Area.	
14.02.03.01	Fire prevention	Evacuation plan and training	Evacuation plan and training for the facility and provide training for evacuation drills to be performed in all areas	ME.20	The evacuation plan was updated in 2021 (2021) and includes all activities. The evacuation plan was updated in 2021 (2021) and includes all activities. The evacuation plan was updated in 2021 (2021) and includes all activities.	Evacuation plan and training for the facility and provide training for evacuation drills to be performed in all areas	
14.02.03.02	Emergency procedures	Emergency	Program a comprehensive emergency plan related to the isolation system in the emergency response for the facility	ME.21	The program was updated in 2021 (2021) and includes all activities. The program was updated in 2021 (2021) and includes all activities. The program was updated in 2021 (2021) and includes all activities.	Program a comprehensive emergency plan related to the isolation system in the emergency response for the facility	
14.02.03.02	Emergency procedures	Emergency and isolation	Chlorine safety emergency and isolation response. The emergency and isolation response was not maintained. The emergency and isolation response was not maintained. The emergency and isolation response was not maintained.	ME.22	The emergency and isolation response was not maintained. The emergency and isolation response was not maintained. The emergency and isolation response was not maintained.	Chlorine safety emergency and isolation response. The emergency and isolation response was not maintained. The emergency and isolation response was not maintained. The emergency and isolation response was not maintained.	
14.02.03.02	Chemical Safety	Chemical storage	Chemical storage. The chemical storage was not maintained. The chemical storage was not maintained. The chemical storage was not maintained.	ME.23	The chemical storage was not maintained. The chemical storage was not maintained. The chemical storage was not maintained.	Chemical storage. The chemical storage was not maintained. The chemical storage was not maintained. The chemical storage was not maintained.	
14.02.03.02	Chemical Safety	Chemical storage	Chemical storage. The chemical storage was not maintained. The chemical storage was not maintained. The chemical storage was not maintained.	ME.24	The chemical storage was not maintained. The chemical storage was not maintained. The chemical storage was not maintained.	Chemical storage. The chemical storage was not maintained. The chemical storage was not maintained. The chemical storage was not maintained.	
14.02.03.01	Fire prevention	Chemical storage	Program fire prevention measures storage in the facility. The fire prevention measures storage in the facility was not maintained. The fire prevention measures storage in the facility was not maintained.	ME.25	The fire prevention measures storage in the facility was not maintained. The fire prevention measures storage in the facility was not maintained. The fire prevention measures storage in the facility was not maintained.	Program fire prevention measures storage in the facility. The fire prevention measures storage in the facility was not maintained. The fire prevention measures storage in the facility was not maintained.	
14.02.03.01	Chemical Safety	MEOS	Chemical Safety. The chemical safety was not maintained. The chemical safety was not maintained. The chemical safety was not maintained.	ME.26	The chemical safety was not maintained. The chemical safety was not maintained. The chemical safety was not maintained.	Chemical Safety. The chemical safety was not maintained. The chemical safety was not maintained. The chemical safety was not maintained.	
14.02.03.02	Chemical Safety	Identification	Chemical Safety. The chemical safety was not maintained. The chemical safety was not maintained. The chemical safety was not maintained.	ME.27	The chemical safety was not maintained. The chemical safety was not maintained. The chemical safety was not maintained.	Chemical Safety. The chemical safety was not maintained. The chemical safety was not maintained. The chemical safety was not maintained.	



